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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,765	01/14/2004	Per Egnelov	030481-0212	1510

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EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	**PAPER NUMBER**
3735	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/756,765	EGNELOV ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11,14-16 and 20-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *9,11,15 and 16* is/are allowed.

6)☒ Claim(s) *1,3-8,10,14 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The allowability of claim 20 regretfully has been withdrawn. See the rejection below for details.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/28/07 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8, 10, 14, and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,246,426 to Lewis et al. Lewis teaches an indicator system comprising a body 22, 74, 92 comprising a passage 42 passing through the body, the body further comprising a duct 82, 108 extending in the body and having a hemostatically sealed blood accommodating chamber 38, 40 (see entire document,

especially figs. 1-6D, 7, and 8B; col. 4, lines 27-48; col. 5, lines 8-42; col. 7, lines 14-49; and col. 9, lines 15-34 of Lewis). The language "hemostatically sealed" is taken to mean that the chamber is sealed so as to prevent the leakage of blood from the chamber, wherein the chamber of Lewis is so sealed (see entire document, especially col. 5, lines 34-37 of Lewis). An insertion tube 14, 70 comprises a distal end portion 14b, 70b adapted to be positioned inside the blood vessel and comprising a fluid communication pathway between a liquid inlet opening 70d near a distal end of the insertion tube and the duct. The insertion tube further comprises an opening at the extreme end of the distal end portion (see entire document, especially figs. 1, 6C, 7, and 8B; col. 4, lines 33-39; col. 5, line 65-col. 6, line 2; col. 6, line 56-col. 7, line 13; col. 7, lines 27-34; col. 9, lines 16-34 of Lewis). A window 24, 26, 92, 106 comprises an at least semi-transparent section configured to enable visual observation of blood entering into the duct via the inlet opening when the inlet opening is located inside the blood vessel (see entire document, especially figs. 4, 5, 6B & C, and 7; col. 5, lines 14-23; col. 8, lines 17-27; col. 10, lines 25-30 of Lewis). An elongated member 16 is further included (see entire document, especially figs. 1, 6A, 6B of Lewis). The passage and fluid communication pathway are adapted to permit the elongated member to be threaded in a substantially straight path therethrough between a distal end of the insertion tube and a proximal end of the body (see entire document, especially figs. 1, 3, and 8B of Lewis). The liquid inlet opening near the distal end of the insertion tube may be uncovered, in that the insertion tube 14, 70 may be removed from the catheter body 192 (see entire document, especially fig. 6C; col. 4, lines 49-53 of Lewis). An outer

dimension of the elongated member 16 is substantially equal to an inner dimension of the insertion tube at the distal end of the insertion tube 14, 70 (see entire document, especially figs. 8B and 10 of Lewis).

As to the limitation, "for visually indicating a pressure of blood inside a blood vessel" in the preamble of claim 1, the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art since Lewis teaches all of the claimed structural limitations and their recited relationships. The system of Lewis is certainly capable of being used to visually indicated a pressure of blood inside a blood vessel.

Regarding claim 3, the duct 82, 108 opens into the chamber via an aperture 84, 86 having a spill-over edge 78, the aperture being located at a level above a bottom surface of the blood accommodating chamber 38, 40, whereby return of flow of blood back into the duct is prevented (see entire document, especially figs. 4, 6B, 6C, and 7 of Lewis). The location of the aperture with respect to the bottom surface of the chamber depends on the orientation in which the device of Lewis is held. The device of Lewis is capable of being held in such a manner. As to the language "whereby return flow of blood back to into the duct is prevented", this language is "results" language wherein prevention of return flow is stated as being a result of the preceding claimed structural features of the invention. Since Lewis teaches all of the claimed structural features of the invention, it is, therefore, assumed that the prior art reference also accomplishes the claimed result. If this is not the case, then it would appear that the applicants have failed to claim some essential element of the invention.

Regarding claim 4, the blood accommodating chamber 38, 40 is located in the body 22, 74, and the body further comprises the insertion tube 14, 70 extending distally of the body (see entire document, especially figs. 1, 4 of Lewis).

Regarding claim 5, the inlet 70d is located on a side of the insertion tube (see entire document, especially figs. 6B & 6C of Lewis).

Regarding claims 6 and 7, the duct extends vertically or horizontally to an aperture 84, 86 opening into the blood accommodating chamber 38, 40 (see entire document, especially figs. 4, 6B, 6C, and 7 of Lewis) wherein the direction of the duct's extension (vertically or horizontally) is merely "intended use" language since it depends on how the device is held. The device of Lewis may be held such that the duct extends vertically or horizontally. In a horizontal position, a portion of the duct 82 extends above a portion 40 of the blood-accommodating chamber 40 to an aperture 86 into the chamber (see entire document, especially figs. 4, 6B, 6C, and 7 of Lewis).

Regarding claim 8, the duct 82, 108 exhibits a varying cross-section over its length (see entire document, especially figs. 7, 8A, and 8B of Lewis).

Regarding claims 10 and 14, the elongated member 16 may be threaded in a substantially straight path through the passage and fluid communication pathway such that the elongated member projects distally past the extreme end of the distal end portion (see entire document, especially figs. 1 and 8B; col. 5, line 61-col. 6, line 51 of Lewis).

Regarding claim 20, Lewis teaches providing an indicator system, said system being described above, and further teaches positioning the distal end portion of the

insertion tube inside the blood vessel and blood appearing in the chamber 38, 40, 106, wherein the appearance of blood in the chamber is a result of the pressure inside the blood vessel (blood pressure) being higher than the pressure inside the chamber (ambient pressure), such that the appearance of blood in the chamber indicates blood pressure in the blood vessel (see entire document, especially col. 5, line 61-col. 6, line 14; col. 8, lines 28-62; col. 10, lines 21-34 of Lewis).

Regarding claims 21-23, the elongated member 16 is considered to be a guide wire, guide rod, or dilator (see entire document, especially col. 4, line 32 of Lewis; also see col. 10, lines 17-38 and figures 3 and 8 of US Patent No. 6,689,070 to Hung which shows a dilator 40 being an elongated member used to advance a catheter into a body opening and similar to the guide wire of Lewis).

Response to Arguments

Applicant's arguments filed 3/28/07 have been fully considered but they are not persuasive.

The applicants argue that Lewis does not disclose or suggest an outer dimension of the elongated member being substantially equal to an inner dimension of the insertion tube at a distal end of the insertion tube. Instead, the applicants claim that the guide wire 16 in Lewis, as shown in figure 8B, is significantly smaller in diameter than the opening at tip 4b, 70b of the device (see pp. 11-12 of the arguments filed 3/28/07). The examiner respectfully disagrees with this assessment. The applicants have not provided any limitations or guidelines as to what constitutes "substantially equal", and

"substantially" is taken to mean for the most part, or essentially. Therefore, according to figures 8B and 10 of Lewis, the outer diameter of the elongated member 16 and the inner diameter of the insertion tube 14, 70 at the distal end of the tube is shown as being substantially, or, for the most part, equal, as evidenced by there being only a small space shown between the elongated member and the insertion tube. Therefore, the rejection of at least claims 1, 10,14, 21 and 22 under 35 U.S.C. 102(b) as being anticipated by Lewis still stands.

Allowable Subject Matter

Claims 9, 11, 15, and 16 are allowed. The allowability of claims 9 and 15 was addressed in a previous Office action filed 4/20/05 and is repeated below for convenience. The allowability of claims 11 and 16 was addressed in a previous Office action filed 6/30/06 and is also repeated below for convenience

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 9, the primary reason for allowance is the inclusion of the duct becoming narrower in the direction towards the blood accommodating chamber, which is not found in the prior art references. In the examiner's opinion, it would not have been obvious to make the duct of Lewis narrow in the direction toward the blood accommodating chamber, particularly in light of the applicants' disclosure that the narrowing of the duct is being useful for reducing sensitivity in the detection of pulsation

(see paragraph 51 of the applicants' specification) and clearly not a mere design consideration.

Regarding claim 11, the primary reason for allowance is the inclusion of the duct first becomes progressively narrower and then becomes progressively wider, which is not found in the prior art references. In the examiner's opinion, it would not have been obvious to make the duct of Lewis becomes progressively narrower and then become progressively wider, particularly in light of the applicants' disclosure that the that the narrowing of the duct is useful in reducing the sensitivity in detection of pulsation and widening of the duct is useful in that it can accommodate a wider pressure range (see paragraphs 51-53 of the applicants' specification) and clearly not a mere design consideration.

Regarding claim 15, the primary reason for allowance is the inclusion of the blood accommodating chamber and the duct being dimensioned such that a counter-pressure therein when blood enters will cause a blood meniscus at a lowest possible systolic pressure to be located approximately at the spill-over edge, which is not found in the prior art references. The applicants disclose that such dimensioning ensures that the chamber volume is adapted to include the expected pressure ranges and all such pressures would be visually detectable (see paragraphs 42-44 of the applicants' specification).

Regarding claim 16, the primary reason for allowance is the inclusion of the blood accommodating chamber and the duct being dimensioned such that a counter-pressure therein when blood enters will cause a blood meniscus at a lowest possible

systolic pressure to be located within the window, which is not found in the prior art references. The applicants disclose that such dimensioning ensures that all expected pressure ranges may be visually detectable (see paragraphs 42-44 of the applicants' specification).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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